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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,622	05/16/2006	Susanne Moira Brown	6947-75757-01	9395

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EXAMINER	
SHIN, DANA H	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
10/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/579,622	BROWN ET AL.	
	Examiner	Art Unit	
	Dana Shin	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-17,19-28,33-36,42,44,45,47,90 and 91* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-17,19-28,33-36,42,44,45,47,90 and 91* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application/Amendment/Claims

This Office action is in response to the communications filed on August 21, 2007.

Currently, claims 1-3, 5-17, 19-28, 33-36, 42, 44-45, 47, and 90-91 are pending and under examination on the merits.

The following rejections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

Maintained Rejections

Claim Rejections - 35 USC § 103

Claims 1-3, 5-17, 19-28, 33, 36, and 47 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Nemunaitis in view of Tang et al. and Jacobs et al. for the reasons of record as set forth in the Office action mailed on April 24, 2007 and for the reasons stated below.

Applicant's arguments filed on August 21, 2007 have been fully considered but they are not persuasive. Applicant argues that the combined references do not make the claimed invention obvious because none of the references teaches squamous cell carcinoma related oncogene.

Although it is true that none of the cited references expressly state "squamous cell carcinoma related oncogene", the nucleotide sequence of SEQ ID NO:22 of Tang et al. meets the structural limitation that defines the claimed antisense squamous cell carcinoma related oncogene because the nucleotide sequence of SEQ ID NO:22 of Tang et al. is indeed at least 70% identical to the nucleotide sequence of SEQ ID NO:1 claimed in the instant case. Since Tang et al. expressly taught that their SEQ ID NO:22 can be used as an antisense polynucleotide molecule by placing it in an appropriate vector for downregulation of its target gene expression, it would have been obvious to one of ordinary skill in the art at the time the invention was made to insert the antisense polynucleotide sequence of SEQ ID NO:22 of Tang et al. into the HSV mutant virus vector of Nemunaitis by using the recombination technology of Jacobs et al. with a reasonable expectation of success.

Applicant further argues that there is no teaching in Tang et al. that an antisense molecule comprising SEQ ID NO:22 would be useful for specifically treating squamous cell carcinoma. Applicant's attention is directed to the fact that this alleged feature of "specifically treating squamous cell carcinoma" is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In view of the foregoing, this rejection is maintained.

Claims 1-3, 9-17, 33-36, 42, 44-45, 47, and 90-91 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Toyoizumi et al. in view of Estilo et al. and Jacobs et al. for the

reasons of record as set forth in the Office action mailed on April 24, 2007 and for the reasons stated below.

Applicant's arguments filed on August 21, 2007 have been fully considered but they are not persuasive. Applicant argues that Toyoizumi et al. do not teach whether herpes simplex virus can be successfully used to deliver antisense molecules to downregulate a gene. Contrary to applicant's argument, Toyoizumi et al. expressly taught the *in vivo* anti-cancer therapeutic efficacy of HSV mutant vectors carrying a piece of exogenous gene has been widely known in the art. See page 3014. Therefore, since an antisense polynucleotide molecule is a piece of exogenous gene, and since the ability of HSV mutant vectors to deliver exogenous genes into target tumor cells thereby treating cancer was known in the art, one of ordinary skill in the art would have had a reasonable expectation of using the HSV mutant vectors of Toyoizumi et al. to deliver antisense molecules at the time of the invention. Further, applicant asserts that Estilo et al. do not state "antisense" therapy by targeting SCCRO but rather state "SCCRO may be a prognostic factor and provide a basis for the development of novel anti-tumor strategies", and therefore, one of ordinary skill in the art "may interpret this statement as meaning that the ability to provide a prognosis based on the observation of SCCRO expression opens the way to new anti-tumor strategies that have nothing to do with SCCRO." Applicant's own interpretation of the statement in the reference of Estilo et al. is acknowledged; however, applicant's interpretation of the teachings contained in the very statement appears to be oversimplified and narrow. The context of the isolated statement must be interpreted in light of the general content of the teachings of Estilo et al., which clearly show that the expression level of SCCRO is significantly increased in malignant squamous cell carcinoma tissues and that exogenous overexpression of SCCRO stimulate tumor metastasis in nude mice. As such, the entire reference

of Estilo et al. is devoted to showing the correlation between SCCRO mRNA expression level and the status of squamous cell carcinoma metastasis. From these experimental data, Estilo et al. suggest that SCCRO may provide a basis for anti-tumor therapeutic development. It is therefore unclear how the "anti-tumor" therapeutic strategies suggested by Estilo et al. have nothing to do with SCCRO as applicant alleges. Applicant further emphasizes that the therapeutic strategies of Estilo et al. were uncertain. Applicant should note that the passages pointed out by applicant (see page 21 of applicant's remarks) pertain to therapeutic strategies for treating lymphatic metastasis, and therefore are irrelevant and out of scope in the instant case. As stated above and in the previous Office action, Estilo et al. expressly taught that SSCRO plays a prominent role in disease progression of squamous cell carcinoma of the oral tongue.

Applicant alleges that a *prima facie* case of obviousness has not bee established because none of the cited references teaches "antisense to SCCRO" nor any one of them suggests "motivation to produce the invention as claimed", hence, there would be "no expectation that such an invention would be successful". Although it is true that none of the cited references teaches the term "antisense to SCCRO", Estilo et al. clearly suggested that reducing SCCRO mRNA expression would reduce the disease progression of squamous cell carcinoma of the oral tongue. Furthermore, antisense molecules had been known in the art for decades by the time the claimed invention was made as the traditional, standard, and conventional means to downregulate target mRNA expression. See for example Zamecnik et al. (*PNAS,* 1978, 75:280-284). Further, use of antisense technology to inhibit the expression/function of protooncogenes has been an art-accepted knowledge for many years. See for example Holt et al. (*PNAS,* 1986, 83:4794-4798). Since Estilo et al. suggested that SCCRO is a protooncogene for squamous cell carcinoma and that SCCRO provides a new anti-tumor therapeutic tool for squamous cell

carcinoma, one of ordinary skill in the art at the time of the invention would have been "motivated" to use the art-recognized knowledge that antisense technology to downregulate the expression of the protooncogene SCCRO. Further, since the mutant HSV vectors of Toyoizimi et al. were known to be useful to carry exogenous genes to target tissues/cells for cancer therapy, and since the molecular technology to produce a desired HSV vectors for gene therapeutic applications was available as taught by Jacobs et al., the skilled artisan would have had a "reasonable expectation of success" in making the claimed product.

Accordingly, this rejection is maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana Shin whose telephone number is 571-272-8008. The examiner can normally be reached on Monday through Friday, from 8am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Examiner
Art Unit 1635

/J. E. Angell/
Primary Examiner
Art Unit 1635